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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------------|----------------------|---------------------|------------------|
| 10/751,266 | 01/02/2004 | Ross S. Tsugita | RMI-5730CON6 | 7452 |
| John Christophe | 7590 10/20/200 er James | EXAMINER | | |
| Edwards Lifesciences LLC | | | TRUONG, KEVIN THAO | |
| One Edwards Way, Legal Department Irvine, CA 92614 | | | ART UNIT | PAPER NUMBER |
| , | | | 3734 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 10/20/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | | |
|--|---|----------------|--|--|--|--|
| Office Action Comments | 10/751,266 | TSUGITA ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Kevin T. Truong | 3734 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>RCE</u> | and Amendt. 07/02/2008. | | | | | |
| | action is non-final. | | | | | |
| <i>;</i> — | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| · | pance Quayre, 1000 0.21 1.1, 10 | 3 3.3.2.3. | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-28,37-98,107-115 and 121-150 is/are pending in the application. 4a) Of the above claim(s) 1-28, 37-78, and 84-98 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 79-83,107,108 and 121-150 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other: | te | | | | |

Application/Control Number: 10/751,266 Page 2

Art Unit: 3734

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2008 has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 79-83, 107-108, and 121-150 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaganov et al. (U.S. 5,876,367).

Kaganov et al disclosed substantially as claimed in figures 3 and 6, a sleeve (14) adapted to be disposed substantially at a distal end of the filter device (42), wherein the filter (42) includes an expansion frame supporting a filter mesh (col. 2, lines 28-31), wherein the sleeve (14) being adapted to apply a restraining force to the plurality of struts of the filter device (42) to prevent the plurality of the struts

Application/Control Number: 10/751,266 Page 3

Art Unit: 3734

from extending outwardly; an actuating member (at 43) coupled to the sleeve (14) and being connected to the filter device (42) and move relative to sleeve (14) to release the struts of the filter device (42); and also, a balloon (35) mounted on the outer surface of sleeve (14) is clearly capable of being sized to be inserted into a stenotic lumen of a blood vessel and being expanded such that the stenotic lumen of the blood vessel is less stenotic after expansion of the balloon (35).

Response to Arguments

3. Applicant's arguments filed 07/02/2008 have been fully considered but they are not persuasive. In response to applicant's argument that the balloon of Kaganov is not the sized to be inserted into a stenotic lumen of a blood vessel and being expanded such that the stenotic lumen of the blood vessel is less stenotic after expansion of the balloon, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/ Primary Examiner, Art Unit 3734